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Request for grant of a patent

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01 OCT 1999

1. Your Reference **CGP/PG3786**

2. Patent application number **9923273.8**
(The Patent office will fill in this part)

3. Full name, address and postcode of the or of each applicant (underline all surnames)
**GLAXO GROUP LIMITED
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UNITED KINGDOM**

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its corporation

473587003ma

4 Title of the invention **MEDICAMENT DELIVERY SYSTEM**

5 Name of your agent (if you have one) **DR CHRISTOPHER GERARD PIKE
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"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

Patents ADP number (if you know it)

7497928002ma

6. If you are declaring priority from one or more earlier patent applications, give the country and date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country	Priority application number (if you know it)	Date of Filing (day / month / year)
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7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing (day / month / year)
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8. Is a statement of inventorship and of right to grant a patent required in support of this request? (Answer yes if:
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d)) **YES**

Medicament delivery system

5 The present invention relates to a system for the delivery of medicament having an electronic data management system. The system is capable of wireless communication with a gateway to a network computer system to enable communication of data between the network computer system and the electronic data management system.

10 It is common prescribing practice for a doctor to prescribe a patient with medicament in a medicament dispenser together with instructions for patient administration of the medicament according to a defined treatment regime. The patient typically therefore, receives instructions relating to the correct use of the dispenser together with recommended dosing amounts, dose intervals and
15 treatment period. The patient is then trusted to follow the treatment regime as set by the doctor.

20 A limitation associated with this practice is that the treatment regime is set at the time of prescription and can therefore not account for changes in the patient's condition over the treatment period. A further limitation associated with this practice is that the onus is on the patient to comply with the doctor's instructions. Occasionally, patients will forget to take the medicament or will vary the treatment regime in an unpredictable manner with possible consequences for the success of the treatment.

25 A variation on the above-described prescribing practice involves the use by a patient of a diagnostic device which enables data relating to their medical condition to be gathered on a regular basis. This data may for example, be collected prior to administration of any medicament and a correct dose amount
30 calculated on the basis of the diagnostic data. An example of this practice would be that of a diabetic who checks their blood-sugar levels in order to calculate a required dose of insulin.

35 In developments of the practice variation, the diagnostic device may be integrated with the delivery system. Information relating to the patient's condition

electronic data management system; and a communicator for wireless communication with a gateway to a network computer system to enable transfer of data between the network computer system and the electronic data management system.

5

The electronic data management system comprises a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.

10

Preferably, the communicator enables two-way transfer of data between the network computer system and the electronic data management system.

15

Preferably, the data is communicable between the network computer system and the electronic data management system in encrypted form. All suitable methods of encryption or partial encryption are envisaged. Password protection may also be employed.

20

Preferably, the communicator employs radiofrequency or optical signals.

In one aspect, the communicator communicates directly with the gateway.

25

In another aspect, the communicator communicates with the gateway via a second communications device. Preferably, the second communications device is a telecommunications device, more preferably a cellular phone or pager.

30

Preferably, the communicator communicates with the second communications device using spread spectrum radiofrequency signals. A suitable spread spectrum protocol is the Bluetooth (trade mark) standard which employs rapid (e.g. 1600 times a second) hopping between plural frequencies (e.g. 79 different frequencies). The protocol may further employ multiple sending of data bits (e.g. sending in triplicate) to reduce interference.

35

In one aspect, the network computer system comprises a public access network computer system. The internet is one suitable example of a public access network computer system, wherein the gateway can be any suitable gateway

In another aspect, the remote information source is a pharmacy. Information transferred from the pharmacy may thus, comprise information relating to the medicament product. Information sent to the pharmacy may thus include prescription requests which have been remotely pre-authorized by the medicament prescriber.

In a further aspect, the remote information source is an emergency assistance provider, for example a hospital accident and emergency service or an emergency helpline or switchboard. The information may thus, comprise a distress or emergency assist signal which requests emergency assistance.

In a further aspect, the remote information source is a manufacturer of medicament or medicament delivery systems. Information transferred to the system may thus, comprise product update information. The system may also be configured to feed information back to the manufacturer relating to system performance.

In a further aspect, the remote information source is a research establishment. In a clinical trials situation, information may thus be transferred relating to the trials protocol and information relating to patient compliance fed back to the research establishment.

In a further aspect, the remote information source is an environmental monitoring station. Information relating to weather, pollen counts and pollution levels may thus be made accessible to the system.

Preferably, the system additionally comprises a datalink for linking to a local data store such as a personal computer or set-top box to enable communication of data between the local data store and the microprocessor. Preferably, the datalink comprises an infrared emitter and sensor.

Preferably, the system additionally comprises a data input system for user input of data to the electronic data management system. More preferably, the data input system comprises a keypad.

movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

5 In another aspect, the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

In a further aspect, the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

10 In a further aspect, the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user. The temperature of the inhaled and exhaled part of the breath cycle varies and may, thus, be used as a measurement tool.

15 In a further aspect, the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user. The moisture content of the inhaled and exhaled part of the breath cycle varies and this also may be used as a measurement tool.

20 In a further aspect, the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user. The chemical profile of the inhaled and exhaled part of the breath cycle varies and this further may be used as a measurement tool.

25 Preferably, the breath data includes breath cycle data or peak flow data.

Preferably, the system additionally comprises an actuator for actuating the dispensing mechanism, said actuator being actuatable in response to a trigger signal from the transmitter.

30 Preferably, the electronic data management system includes a predictive algorithm or look-up table for deriving from the breath data when to transmit the trigger signal. For example, a real-time analysis of the patient breath waveform may be made and the trigger point derived by reference to that analysed waveform.

35

According to another aspect of the present invention there is provided a data communicator for use with a medicament dispenser comprising an electronic data management system; a communicator for communicating with a gateway to a network computer system to enable communication of data between the
5 network computer system and the microprocessor; and a coupling mechanism for coupling the data communicator to the medicament dispenser.

The electronic data management system comprises a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter
10 for transmitting a signal relating to the data or the outcome of an operation on the data;

According to another aspect of the present invention there is provided a kit of parts comprising a data communicator as described above and a medicament
15 dispenser comprising a medicament container; and a dispensing mechanism for dispensing medicament from the medicament container.

The data communicator may for example, be mechanically coupled to the medicament dispenser by any suitable mechanical mechanism including grip mechanisms and snap-fit mechanisms. In a preferred aspect, the data
20 communicator forms a snap-in module and the dispenser is shaped for receipt of the module.

In aspects, the data communicator or any distinct device aspects of the system may be adapted to be worn on the body of the user. Examples would include belt attachable devices, devices in the form of watches for wrist or leg attachment and devices attachable as jewellery. Suitable body attachment means will be
25 incorporated as required.

Embodiments of systems according to the invention will now be described with reference to the accompanying drawings in which:
30

Figure 1. is a schematic representation of a first system in accord with the present invention; and
35

Figure 2. shows a variation of the system of Figure 2. The system comprises standard-form metered dose inhaler for the delivery of inhalable medicament comprising tubular housing 110, an aerosol container 112 and dispensing outlet 114. Operation of the inhaler is as described above with reference to Figure 1.

The dispenser includes an electronic data management and communications system in the form of a chip 140 comprised within the housing 110. Display 130 allows for limited display data from the electronic data management system. The dispenser readily communicates via chip 140 to palmtop computer 170. The communication is via spread spectrum radiofrequency signals operable over a relatively short range (e.g. up to ten metres). The palmtop computer 170 has a more sophisticated display 172 including a graphical user interface comprising menu-entry screens from which selections may be made using toggle menu-button 174.

The user accesses the electronic data management system 140 of the dispenser through the palmtop computer 170. The palmtop computer 170 itself, can communicate through a telecommunications link with computer network system 150. The computer network system 150 comprises a secure extranet computer system. As in Figure 1, remote information sources may also have access to the extranet. Two-way data transfer is possible between the electronic data management system and the computer network system 150 via the communications links with the palmtop computer 170. Information transfer is thus possible between the electronic data management system 140, palmtop computer 170 and any of the remote information sources.

The system of the invention is in one aspect suitable for dispensing medicament for the treatment of respiratory disorders such as disorders of the lungs and bronchial tracts including asthma and chronic obstructive pulmonary disorder (COPD).

Appropriate medicaments may be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or

features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

6. A system according to any of claims 1 to 4, wherein the communicator communicates with the gateway via a second communications device.

5 7. A system according to claim 6, wherein the second communications device is a telecommunications device.

8. A system according to claim 7, wherein the telecommunications device comprises a cellular phone or pager.

10 9. A system according to any of claims 6 to 8, wherein the communicator communicates with the second communications device using spread spectrum radiofrequency signals.

15 10. A system according to any of claims 1 to 9, wherein the network computer system comprises a public access network computer system.

20 11. A system according to any of claims 1 to 9, wherein the network computer system comprises a private access network computer system and the gateway is a secure gateway.

25 12. A system according to any of claims 1 to 11, wherein the communicator enables communication with a user-specific network address in the network computer system.

13. A system according to claim 12, wherein the user-specific network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address.

30 14. A system according to either of claims 12 or 13, wherein the user-specific network address is accessible to a remote information source such that information from said remote information source can be made available thereto.

25. A system according to any of claims 1 to 24, additionally comprising a data input system for user input of data to the electronic data management system.

5 26. A system according to claim 25, wherein said data input system comprises a keypad.

10 27. A system according to any of claims 1 to 26, additionally comprising a display for display of data from the electronic data management system to the user.

15 28. A system according to any of claims 1 to 27, wherein said electronic data management system includes a predictive algorithm or look-up table for calculating the optimum amount of medicament to dispense.

29. A system according to claim 28, wherein the memory includes a dose memory for storing dosage data and reference is made to the dose memory in calculating the optimum amount of medicament to dispense.

20 30. A system according to any of claims 1 to 29, additionally comprising a selector for selecting the amount of medicament to dispense from said dispensing mechanism.

25 31. A system according to claim 30, wherein the selector is manually operable.

32. A system according to claim 31, wherein the selector is operable in response to a signal from the transmitter.

30 33. A system according to any of claims 1 to 32, additionally comprising a detector for detecting dispensing from the medicament container, wherein said detector communicates dispensing data to the electronic data management system.

44. A system according to any of claims 35 to 42, wherein said breath data includes peak flow data.

5 45. A system according to any of claims 35 to 44, additionally comprising an actuator for actuating the dispensing mechanism, said actuator being actuable in response to a trigger signal from the transmitter.

10 46. A system according to claim 45, wherein the electronic data management system includes a predictive algorithm or look-up table for deriving from the breath data when to transmit the trigger signal.

15 47. A system according to any of claims 35 to 46, wherein said medicament container is an aerosol container and the dispensing mechanism is an aerosol valve.

48. A system according to any of claims 35 to 46, wherein said medicament container is a dry-powder container.

20 49. A system according to any of claims 45 to 48, wherein said actuator comprises an energy store for storing energy which energy is releasable to actuate the dispensing mechanism of the medicament container.

25 50. A data communicator for use with a medicament dispenser comprising an electronic data management system comprising

a memory for storage of data;

30 a microprocessor for performing operations on said data; and

a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data;

ABSTRACT

5 There is provided a system for the delivery of medicament comprising a
medicament container; a dispensing mechanism for dispensing medicament
from the medicament container; and a communicator for wireless communication
with a gateway to a network computer system to enable communication of data
between the network computer system and the electronic data management
system. The electronic data management system comprises a memory for
storage of data; a microprocessor for performing operations on the data; and a
10 transmitter for transmitting a signal relating to the data or the outcome of an
operation on the data.

Fig. 1

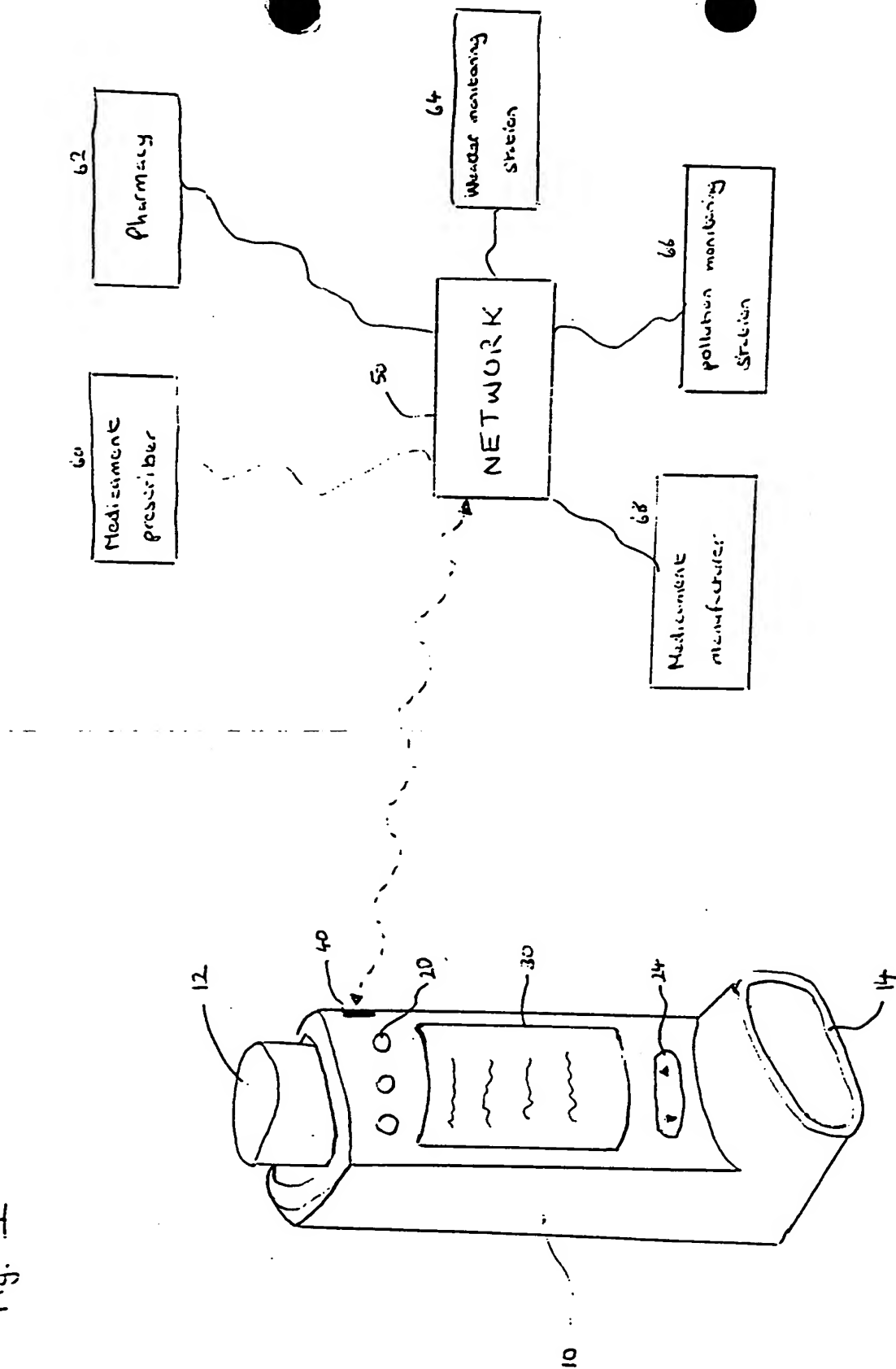


Fig 2.

